

The

Atty. Dkt. No. 056859-0196

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

H. SIVARAMAN et al.

Title:

PROCESS FOR PRODUCTION OF LARGE AMOUNT OF PENICILLIN V ACYLASE

Appl. No.:

10/812,387

Filing Date:

3/30/2004

Examiner:

Unassigned

Art Unit:

1652

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

A copy of Document A6 is not available to applicants' representative at this time. As soon as this document becomes available, it will be forwarded to the US Patent and Trademark Office.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 16, 2005

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: Facsimile:

(202) 672-5490 (202) 672-5399

Michael D. Kaminski Mathew Malkeen Attorney for Applicant Registration No. 32 904

Registration No. 32,904

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

number.	5					
	Substitute for f	orm 1449B	/PTO		Complete if Known	2 10 1
₹,	INFORMATIO	N DISCLO	SURE	Application Number	10/812,387	/
,	STATEMENT	BY APPLI	CANT	Filing Date	3/30/2004	MAR 1 6 2005
	Date Submitted	· March 16	3 2005	First Named Inventor	Hephzibah SIVARAI	MANE 2003 &
	Date Submitted	. Maich it	5, 2005	Group Art Unit	1652	E ST
	(use as many she	eets as ne	cessary)	Examiner Name	Unassigned	PADEMARK
Sheet	1	of	1	Attorney Docket Number	056859-0196	MOENI

U.S. PATENT DOCUMENTS							
Examiner Initials*	<u> </u>	U.S. Patent Document			Date of Publication of	Pages, Columns, Lines, Where Relevant	
	Cite No. ¹	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	

	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No. ¹	Fore Office ³	eign Patent D Number ⁴	ocument Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A1	BOMSTEIN et al., "Automated colorimetric determination of 6-aminopenicillanic acid in fermentation media," ANALYTICAL CHEMISTRY, Vol. 37, 1965, pp. 576-578.	
	A2	CLARIDGE et al., "Bacterial Penicillin Amidase," NATURE, Vol. 187, No. 4733,. 1960, pp. 237-238.	
	A3	OLSSON et al., "Molecular Cloning of <i>Bacillus sphaericus</i> Penicillin V Amidase Gene and Its Expression in <i>Escherichia coli</i> and <i>Bacillus subtilis</i> ," NATURE, Vol. 49, No. 5, 1985, pp. 1084-1089.	
	A4	OLSSON et al., "Sequencing and heterologous expression of the gene encoding penicillin V amidase from <i>Bacillus sphaericus</i> ," GENE, Vol. 45, 1986, pp. 175-181.	
	A5	ROLINSON et al., "Formation of 6-Aminopenicillanic Acid from Penicillin by Enzymatic Hydrolysis," NATURE, Vol. 187, No. 4733, 1960, pp. 236-237.	
	A6	SAKAGUCHI et al., "A Preliminary Report on a New Enzyme Penicillin Amidase," J. AGR. CHEM. SOC. JAPAN, Vol. 23, 1950, p. 411.	
	A7	SAMBROOK et al., MOLECULAR CLONING: A Laboratory Manual, Vol. 1, 1988, pp. 1.82-1.84 and Table of Contents.	
· · · · · · · · · · · · · · · · ·	A8	SHEWALE et al., "Evaluation of determination of 6-aminopenicillanic acid by p-dimethyl aminobenzaldehyde," BIOTECHNOLOGY TECHNIQUES, Vol. 1, No. 1, 1987, pp. 69-72.	
	A9	SURESH et al,. "Penicillin V acylase crystal structure reveals new Ntn-hydrolase family members," NATURE STRUCTURAL BIOLOGY, Vol. 6, No. 5, May 1999, pp. 414-416.	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.